MAY - 3 2000

Sectra Document Number: 3-00.336-1.0

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

K001140

Date Prepared:

4 April 2000

Submitter's Information:

Sectra Imtec AB
Teknikringen 2
SE-583 30 Linköping
Sweden
Phone: +1 46 13 23 52 00
Fax: +1 46 13 21 21 85

Trade Name, Common Name, Classification:

Trade Name:	IDS5 Image Display System
Common Name:	Digital Imaging System
Classification Name:	System, Image Processing, Accessory

Predicate Device:

Applicant:	Sectra Imtec AB
510(k) Number:	K991643
Device:	IDS4 v3.2 Image Display System

Device Description:

The IDS5 Image Display System is mainly a software product. It is used for visualization and processing of digital radiology images. The system runs under the Window NT operating system. The requirements on hardware are quite ordinary for a system used for displaying images. Most notably two or more monitors can be used.

Indications for Use:

The Sectra IDS device is intended for the manipulation and displaying of x-ray images. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

Device options make possible telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics:

The IDS5 system will run on Windows NT operating system for PCs, (as a minimum and depending upon system configuration).

Performance Data:

The subject and predicate devices both use standard data communications controls to detect errors. The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – POSIX standard for Information Processing, FCC Part 15 sub-part B class A, IEEE 802.3 – Ethernet, LAN Interface Standard, ACR/NEMA Digital Imaging Communications In Medicine version 3.0.

Conclusion:

Similar to the predicate device, the IDS5 system does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. The device and the predicate device share the same certification or conformance to performance standards and both function as Image Management Systems. Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

Peter Andersson
Regulatory Assurance Manager
Sectra Imtec AB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Sectra Imtec AB
C/O Herman Oosterwijk
President
Otech Inc.
2001 East Oakshores Drive
Crossroads, TX 76227

Re: K001140
IDS5 Image Display System
Dated: April 4, 2000
Received: April 10, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Oosterwijk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number: K001140

Device Name: IDS (Image Display System) by Sectra Imtec AB

Indications For Use:

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Device options make possible telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001140